IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Abraham J. Domb and Joseph S. Wolnerman

Serial No.: 10/083,413 Art Unit: 1655

Filed: February 27, 2002 Examiner: Flood, Michele C.

For: *ABSORBABLE SOLID COMPOSITIONS FOR TOPICAL TREATMENT OF ORAL MUCOSAL DISORDERS*

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL REPLY TO EXAMINER'S ANSWER

Sir:

This is a reply brief to the Examiner's Answer mailed March 14, 2007 and the Supplemental Examiner's Answer mailed August 29, 2007 in the above-referenced application. A Request for Oral Hearing was submitted with the Reply Brief filed on May 14, 2007. The Commissioner was previously authorized to charge $500, the fee for a Request for Oral Hearing for a small entity, to Deposit Account No. 50-3129.

It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

(7) CLAIMS ON APPEAL

Applicants acknowledge the minor errors in the claims cited by the Examiner in the Supplemental Examiner's Answer. The claims on appeal are provided in the appendix at the end of this brief.

(9) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(1) whether claims 1-4, 6, 15-17, 22-24, and 38 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue").

(2) whether claims 1-3, 15-17, 22-24, 26, and 38 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 4,226,848 to Nagai *et al.* ("Nagai").

(3) whether claims 1-4, 6-12, 15-17, 19, 22-24, and 38 under 35 U.S.C. 103(a) over Inoue in view of U.S. Patent No. 5,939,050 to Iyer ("Iyer") and U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman"), with evidence by Lawless.

(10) ARGUMENT

Appellants affirm all of the arguments made in the Appeal Brief.

(1) Rejections Under 35 U.S.C. § 102

Claims 1-4, 6, 15-17, 22-24, and 38 were rejected as being unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue"). Claims 1-3, 15-17, 22-24, 26, and 38 were rejected as being unpatentable under 35 U.S.C. § 102(b) over U.S. Patent No. 4,226,848 to Nagai *et al.* ("Nagai").

Analysis

a. U.S. Patent N o. 4,772,470 to Inoue et al. ("Inoue")

Claim 1, 4, 6, 15-17, and 23-24 are not anticipated by U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue")

Inoue describes an oral bandage comprising a soft adhesive film comprising a mixture of a polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer and having incorporated therein a topical drug (abstract). The oral bandage may solely contain the adhesive film or may further contain a soft film support in combination with the adhesive film (col. 8, lines 30-33).

In the Examiner's answer, the Examiner states that "since Inoue clearly teaches incorporating topical drugs into the prior art composition in an amount from 0.0001 to 35% by weight based on the oral preparation, the remaining weight portion of the prior art composition comprising the bioadhesive carrier is deemed to be in an amount encompassed by about 40 to 99% based on the weight of the composition "(*see* page 13, lines 3-9). The Examiner provides no evidence to support this statement.

Indeed, this statement is contradicted by the disclosure in the patent. Inoue discloses that in addition to the active agent, the composition can contain a basic substance to neutralize the polycarboxylic acid (col. 6, lines 41-60). The film can also contain other additives, such as colorants, flavorants, and/or softening agents (col. 10, lines 5-14), as well as residual solvent from the casting process.

Further, the Examiner fails to address the applicants' arguments presented in the appeal brief regarding the fact that the examples describe laminating the polycarboxylic acid-polyvinyl acetate film to a support. No information is given regarding the weight of the support film, thus the weight percent of the bioadhesive material cannot be determined. Inoue does not disclose or suggest a solid, self-bioadhesive composition comprising a pharmaceutically acceptable carrier comprising a mucoadhesive synthetic polycarboxylic acid polymer in an amount from about 40 to 99 percent based on the weight of the whole composition.

As discussed above, the films described in Inoue are prepared from blends of polyacrylic acid or anhydride and polyvinyl acetate. Polyvinyl acetate is non-degradable. The films in Inoue must be removed from the mouth after the active agent has been released. In contrast, the claimed compositions contain a bioadhesive carrier containing a polycarboxylic acid carrier, which is degradable over time. The claimed compositions swell initially after administration and then erode over time until the composition is eliminated from the site of administration. Accordingly, claims 1, 4, 6, 15-17, and 23-24 are novel over Inoue.

Claim 2, 3, and 38 are not anticipated by Inoue

The compositions described in Inoue are films. The films described in Inoue are prepared by heating at temperatures between 60°C and 120°C. Under such conditions, herbal extracts tend to deteriorate, significantly altering the properties of the agents contained in the extract. In contrast, the claimed compositions are prepared by compression molding at room temperature to form tablets. The films described in Inoue are cast from solutions containing

organic solvents, which may adversely affect the herbal active agents. In contrast, the claimed compositions are prepared by compressing a mixture of dried powders.

Further, Inoue does not disclose or suggest disks having the diameters and thicknesses specified in claims 2 and 3 or a composition wherein the surface area is from about 0.4 to 3 cm^2 as defined in claim 38. The Examiner alleges that the films described in Inoue have a thickness of at least 5 μm, which encompasses larger thickness, such as 400 μm. Specifically, the Examiner alleges that Inoue discloses films having a width from 7 to 15 mm and diameter ranging from 5 mm to 20 mm and cites col. 8, lines 45-61 as support for this allegation. Col. 8, lines 45-61 discloses the total thickness of the supporting film **and** the thickness of the composite film (thickness of the adhesive film plus thickness of the support film). The thickness of the support film is from 10 to 100 μm (0.01 to 0.1 mm) (col. 8, lines 53-55). The thickness of the composite film is from 30 to 150 μm (0.03 to 0.15 mm). These thicknesses are not within the ranges specified in claims 2 and 3. Inoue goes on to state that "a film having a thickness exceeding 100 μm tends to produce a feeling foreign to the mouth and to impair softness of the film (col. 8, lines 15-17). Accordingly, claims 2, 3, and 38 are novel over Inoue.

Claims 22 and 26 are not anticipated by Inoue

Claim 22 depends from claim 1 and specifies that the solid bioadhesive carrier is a crosslinked synthetic polycarboxylic acid polymer. Claim 26 depends from claim 22 and specifies that the solid bioadhesive carrier is a polyacrylic acid polymer crosslinked with a polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, or mixtures thereof.

Inoue does not disclose or suggest a composition wherein the solid bioadhesive carrier is one or more crosslinked synthetic polycarboxylic acid polymers. The compositions described in Inoue contain a mixture of a polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer. There is no disclosure in Inoue that the polymers are crosslinked.

The Examiner alleges that neutralizing polymers using polyvalent metal salts, such as oxides of zinc, calcium, magnesium, and the like inherently causes crosslinking of the polymer. The Examiner points to the disclosure of Odian (Principles of Polymerization) as support for her argument. A review of the passage marked by the Examiner shows that Odian discloses that neutralization of ethylene copolymers containing 5-10% acrylic or methacrylic acid copolymer with a metal salt yields products referred to as ionomers. Ionomers, according to Odian, act like reversibly crosslinked thermoplastics as a result of *microphase separation* between ionic metal carboxylate and non-polar hydrocarbon segments. The Examiner has misinterpreted Odian. Odian does not disclose that ionomers are cross linked materials; Odian discloses that ionomers **act** like crosslinked polymers due to microphase separation. Even if one could argue that ionomers are crosslinked polymers, there is no disclosure in Inoue or Odian that such a phenomenon occurs in a mixture of polycarboxylic acid polymers and vinyl acetate polymers, which are required in Inoue. Finally, Inoue does not disclose or suggest crosslinked polycarboxylic acid polymers in combination with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylcellulose, hydroxymethyl cellulose, and mixtures thereof as specified in claim 26. Accordingly, claims 22 and 26 are novel over Inoue.

b. U.S. Patent No. 4,226,848 to Nagai

Claims 1-3, 22-24, 26, and 38 are not anticipated by Nagai

Nagai describes pharmaceutical preparations comprising a water-swellable and mucosa-adhesive polymeric matrix comprising about 50% to about 95% by weight of a cellulose ether and about 50 to about 5% by weight of a homo or copolymer of acrylic acid and dispersed therein a pharmaceutically effective amount of medicament (abstract). Nagai does not disclose or suggest a composition containing an herbal active agent wherein the agent is a bioactive herb, a tincture, an essential oil, or mixtures thereof. With respect to herbal extracts, the specification describes the preparation of herbal extracts on page 15, line 17 to page 17, line 2. Herbal extracts are prepared by the extraction of dry herbs. The resulting extracts typically contain several different compounds; the extracts are not a single compound derived from a natural source as described in Nagai. Furthermore, even though the compounds in Nagai cited by the Examiner were originally isolated from natural sources, these compounds are typically prepared synthetically. Accordingly, claims 1-3, 23-24, 26, 27, and 38 are novel over Nagai.

Claims 15-17 are novel over Nagai

Claim 15 is dependent on claim 1 and specifies that the composition further comprises a non-herbal active agent. Claims 16-17 specify particular non-herbal active agents which can be used in the claimed composition in combination with one or more herbal active agents. As discussed above, Nagai does not disclose or suggest compositions containing bioactive herbs,

herbal extracts, tinctures, essential oils, and/or mixtures thereof as required by claim 1. Accordingly, claims 15-17 are novel over Nagai.

(2) Rejections Under 35 U.S.C. § 103

Claims 1-4, 6-12, 15-17, 19, 22-24, and 38 were rejected as being unpatentable under 35 U.S.C. 103(a) over Inoue in view of U.S. Patent No. 5,939,050 to Iyer ("Iyer") and U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman") with evidence provided by Lawless, The Illustrated Encyclopedia of Essential Oils ("Lawless").

Legal Standard

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the examiner: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459 (1966). This standard was recently affirmed by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

The Supreme Court did not obviate the requirement for the references to provide some motivation to combine as applicants have done, with a reasonable expectation of success. Indeed, the examiner's attention is drawn to the following quote by the Court in *KSR*:

> "The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. . . . There is no necessary inconsistency between the test and the *Graham* analysis."

"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

Analysis

1. Inoue in view of Iyer, Friedman, and Lawless

As discussed above, the Court recently reaffirmed the *Graham* factors, which are analyzed below:

(a) Determining the scope and contents of the prior art

Inoue

Inoue describes an oral bandage comprising a soft adhesive film comprising a mixture of a polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer and having incorporated therein a topical drug (abstract). The oral bandage may solely contain the adhesive film or may further contain a soft film support in combination with the adhesive film (col. 8, lines 30-33). Inoue does not disclose or suggest a bioadhesive combination containing a mucoadhesive synthetic polycarboxylic acid in amount from about 40 to about 99% by weight of the whole composition.

The films described in Inoue are prepared from blends of polyacrylic acid or anhydride and polyvinyl acetate. Polyvinyl acetate is non-degradable. The films in Inoue must be removed from the mouth after the active agent has been released. In contrast, the claimed compositions contain a bioadhesive carrier containing a polycarboxylic acid carrier, which is degradable over time. The claimed compositions swell initially after administration and then erode over time until the composition is eliminated from the site of administration.

The films described in Inoue are prepared by heating at temperatures between 60°C and 120°C. Under such conditions, herbal extracts tend to deteriorate, significantly altering the properties of the agents contained in the extract. In contrast, the claimed compositions are prepared by compression molding at room temperature to form tablets. The films described in Inoue are cast from solutions containing organic solvents, which may adversely affect the herbal active agents. In contrast, the claimed compositions are prepared by compressing a mixture of dried powders.

Inoue does not disclose or suggest disks having the diameters and thicknesses specified in claims 2 and 3. Further, Inoue does not disclose or suggest a composition wherein the surface area is from about 0.4 to 3 cm^2 as defined in claim 38.

U.S. Patent No. 5,939,050 to Iyer et al. ("Iyer")

Iyer describes antimicrobial compositions comprising at least two antimicrobial agents which exhibit reduced MIC values relative to the MIC values for the agents making up the combination when measured alone (abstract). Iyer does not disclose a solid, self-bioadhesive formulation for topical application that adheres to the oral mucosal tissue. As noted at col. 7, lines 16-27 and lines 53-61, these formulations are oral rinses, mouth washes or cleansers.

U.S. Patent No. 6,197,305 to Friedman et al. ("Friedman")

Friedman describes an anti-fungal composition containing (a) an extract of botanical materials, the botanical materials including material from Echinacea species and Propolis; and (b) an essential oil (abstract). The composition can be in the form of a mouthwash, a

suppository, or a cream. Friedman does not disclose a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue. The formulations are not bioadhesive. Ingredients such as those at col. 7 are either hydrophobic (such as beeswax) or liquid (glycerin and oil) or contain detergent (such as sodium lauryl sulfate). Table 3 describes a liquid mouthwash formulation, not a solid. Table 4 describes an oral gel primarily of polyethylene glycol, which is not bioadhesive alone. Tables 5 and 6 describe hydrophobic skin cream.

Lawless, The Illustrated Encyclopedia of Essential Oils ("Lawless")

Lawless describes that the essential oil of lemon contains approximately 70% limonene as well as sabinene, myrcene, and pinenes (page 120). Lawless does not disclose a self-bioadhesive composition for topical application that adheres to oral mucosal tissue, nor a homeopathic amount.

The references alone, or in combination, do not disclose each and every element of the claims

Claims 1 and 22-26 are not obvious over Inoue in view of Iyer and Friedman with evidence from Lawless

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974) "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.."). As discussed above,

Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition as required by claim 1.

Inoue does not disclose the composition of claim 1, wherein the carrier is a crosslinked synthetic polycarboxylic acid as required by claims 22 and 26. The films describes in Inoue contain a water-soluble polyacrylic acid, which heavily irritate mucosal tissue. The films in Inoue require the incorporation of a basic material to neutralize the polycarboxylic acid. In contrast, claims 22 and 26 require a crosslinked polyacrylic acid. Crosslinked polyacrylic acids are not soluble in water and therefore do not cause irritation of mucosal tissue. The carrier does not require incorporation of a basic substance to neutralize the polymer. Inoue does not disclose compositions containing enhancer, such as bile acids, as required by claim 25. The remaining references do cure the deficiencies of Inoue. Accordingly claims 1 and 22-26 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

Claims 2, 3, and 38 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims. As discussed above, Inoue does not disclose the bioadhesive composition of claim 1 in the form of a disc having the diameters and thickness specified in claims 2 and 3. Inoue does not disclose the composition of claim 1 having a surface area from about 0.4 to 3.0 cm^2 as required by claim 38.

The Examiner alleges that the films described in Inoue have a thickness of at least 5 μm, which encompasses larger thickness, such as 400 μm. Inoue discloses that the thickness of the polycarboxylic acid-polyvinyl acetate films is preferably in a range from 5 to 100 μm, which is equivalent to 0.005 to 0.1 mm (1 μm = .001 mm). This is not within the range of 0.4 to 2.3 mm in claim 2 or 1 to 2 mm in claim 3.

In fact, Inoue teaches away from the claimed compositions. Inoue discloses that "a film having a thickness exceeding 100 μm tends to produce a feeling foreign to the mouth and to impair softness of the film (col. 8, lines 15-17).

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See *United States v. Adams*, 383 U.S. 39, 52, 148 U.S.P.Q. (BNA) 479, 484, 15 L. Ed. 2d 572, 86 S. Ct. 708 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness"); *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51, 220 U.S.P.Q. (BNA) 303, 311 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851 (1984); *In re Caldwell*, 50 C.C.P.A. 1464, 319

F.2d 254, 256, 138 U.S.P.Q. (BNA) 243, 245 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the applicant).

Inoue discloses that films having a thickness greater than 100 μm tends to produce a feeling foreign to the mouth and to impair softness of the film (col. 8, lines 15-17). In contrast, claims 2 and 3 specify that the composition is in the form of a disk having a thickness of 0.4 to 2.3 mm and 1 to 2 mm, respectively. One or ordinary skill in the art reading Inoue would not be motivated to prepare compositions having a thickness greater than 100 μm as specified in the claims. Iyer, Friedman, and Lawless do not disclose or suggest solid bioadhesive compositions, let alone the diameters and thicknesses specified by the claims. Iyer, Friedman, and Lawless do not cure the deficiencies of Inoue. Accordingly, claims 2, 3, and 38 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

Claims 7-12 and 19 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless

As discussed above, Inoue does not disclose or suggest the bioadhesive composition of claim 1. Claims 7-12 and 19 depend from claim 1. Iyer, Friedman, and Lawless do not cure the deficiencies of Inoue. The Examiner alleges that Inoue discloses each and every element of the claims, except the herbal active agents recited in claims 7-15 and 19 and that the secondary references Iyer, Friedman, and Lawless discloses that the agents recited in claims 7-15 and 19 were useful in the making of topical compositions for the treatment of the oral mucosal tissue. The fact that the references disclose some of the compounds specified in claims 7-15 and 19 is

immaterial. Accordingly, claims 7-12 and 19 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

The results shown in the Examples could not have been predicted in view of the disclosure of Inoue

Under the Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in view of KSR, published by the USPTO on October 10, 2007, combining prior art elements according to known methods is not obvious if the results are unpredictable.

Example 4 in the present application describes the preparation of several tablets containing a powdered herbal extract. The tablets were prepared by compression molding. The compositions were applied **once a day**. The tablets were used by patients suffering from herpetic stomatitis lesions (fever blisters or cold sores) and three patients with apthous ulcers (canker sores), mucosal inflammation, toothache, RAS, and lesions on the lips, tang, and gingiva. Significant improvement was observed within 2-3 days of application. In all cases, the tablets remained on the site of application for 6 hours with slow dissolution of the tablet. Example 6 describes sticker tablets loaded with carnallite and citron oil and benzocaine. 17 patients with recurrent aphthous stomatitis (RAS) were treated by applying the sticker tablet twice a day onto the lesion. The patients reported that soreness and pain was eliminated within three hours and the lesions disappeared within 24 hours. The patients did not report any irritation due to the presence of the sticker tablet.

In contrast, the films described in Inoue had to be applied two-four times/day in order to achieve efficacy (*see* the Examples in Inoue). Further, the samples tended to delaminate or peel, after approximately 4 hours and had to be removed. Finally, Inoue discloses that neutralizing agents must be incorporated into the formulations in order to avoid irritation of the mucosal tissue. One of ordinary skill in the art could not predict the efficacy of the claimed compositions in view of the disclosure of Inoue. Accordingly, claims 1-4, 6-12, 15-17, 19, 22-24, and 38 are not obvious over Inoue in view of Iyer and Friedman with evidence from Lawler.

(8) SUMMARY AND CONCLUSION

Inoue does not disclose a bioadhesive composition comprising a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa. Inoue does not disclose a solid composition in the form of a disc having the dimensions specified in claim 2, 3, and 38.

Nagai does not disclose a solid, bioadhesive composition comprising at least one herbal active agent as defined in claim 1.

Iyer, Friedman, and/or Lawless do not disclose the elements missing from Inoue. Accordingly, the claims are not obvious over these references.

For the foregoing reasons, Appellant submits that claims 1-4, 6-12, 14-17, 19-26, and 38 are patentable.

Respectfully submitted,

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Date: October 29, 2007

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Claims Appendix: Claims On Appeal

1. A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent wherein the herbal active agent is selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof, and

(b) a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

2. The solid composition of claim 1 wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes.

3. The solid composition of claim 1 where the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

4. The composition of claim 1 wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof.

6. The composition of claim 1 wherein the herbal active agent is selected from the group consisting of Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, menthol, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Kramerica, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof.

7. The composition of claim 1, wherein the herbal active agent is an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavendar oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

8. The composition of claim 7, wherein the herbal active agent is an essential oil selected from the group consisting of cinnamon oil, tea-tree oil, citronella oil, and combinations thereof.

9. The composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. The composition of claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. The composition of claim 9, wherein the monoterpene with three unsaturations is a citrus oil selected from the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof.

12. The composition of claim 1, further comprising a salt selected from the group consisting of MgBr2, NaCl, KCl and mixtures thereof.

14. The composition of claim 1 further comprising Carnallite or a salt of Carnallite.

15. The composition of claim 1, further comprising a non-herbal active agent.

16. The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacaine, and etidocaine.

17. The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

19. The composition of claim 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1.

21. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivecaine.

22. The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of crosslinked synthetic polycarboxylic acid polymers and mixtures thereof.

23. The composition of claim 1 wherein the polymer is a copolymer of one or more polymers selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof.

24. (previously presented) The composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

25. The composition of claim 24 wherein the enhancers are selected from the group consisting of bile acids and limonene.

26. The composition of claim 22 wherein the solid bioadhesive carrier is selected from polyacrylic acid polymers crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof.

38. The composition of claim 1, wherein the composition has a surface area ranging from about 0.4 to about 3 cm^2.